

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE LITIGATION)	MDL No. 1456
)	
THIS RELATES TO)	Civil Action No. 01-CV-12257 PBS
)	
STATE OF MONTANA v. ABBOTT LABS.,)	Judge Patti B. Saris
INC., et al.,)	Chief Magistrate Judge Marianne B. Bowler
02-CV-12084-PBS)	

**THE BMS DEFENDANTS' REPLY MEMORANDUM OF LAW IN SUPPORT
OF THEIR MOTION FOR SUMMARY JUDGMENT**

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Defendants Bristol-Myers Squibb Company (“BMS”), Oncology Therapeutics Network Corporation (“OTN”) and Apothecon, Inc. (together “BMS”) respectfully submit this reply to Montana’s opposition (“Opp.”) to their motion for summary judgment and in further support of that motion as to all claims in Montana’s Second Amended Complaint.

Preliminary Statement

The essence of the State’s position is captured in its Introduction: “[T]he State challenges a pervasive scheme whereby BMS reported list prices that **most** buyers did not pay, knowing full well that the list prices would be used to create AWPs that BMS published for use by the Montana Medicaid program” (Opp. at 1 (emphasis in original).) That position is undermined by the following undisputed facts:

- (1) BMS did not make any representations to the State about AWPs.
- (2) BMS simply reported its list prices to industry Publications, who applied their own mark-up factor to calculate and publish AWPs.
- (3) BMS had substantial sales at list price -- indeed, with respect to self-administered drugs (“SADs”), which represent 99% of the BMS transactions at issue in this case, there were virtually no discounts to pharmacies below list price.
- (4) BMS did not control how the Publications calculated AWPs.

Rather than dispute these facts, the State tries to sidestep them by raising a number of red herrings:

- (1) The State claims that “BMS **itself** published AWPs, thereby making affirmative misrepresentations **itself**.” (Opp. at 11 (emphasis in original).) **The State does not claim, much less show, that BMS published AWPs to it, as opposed to using them for internal purposes and making them available to doctors, who did not use them to make any representations to the State.**

- (2) The State claims that BMS's list prices, or WLPs, were inaccurate because BMS offered "confidential discounts" to customers. (Opp. at 13.) **The State acknowledges, however, that "the vast majority of BMS's revenues were generated at prices within 5% of WLP" (Id. at 14.) Thus, there were no discounts and, in any event, there is no legal requirement that a list price reflect discounts.**
- (3) The State claims that "BMS was not required to volunteer its WLPs to pricing compendia, like First DataBank, which supplied AWPs to Montana Medicaid." (Opp. at 9.) **This ignores the undisputed testimony that a drug will not be eligible for reimbursement unless it is reported to the Publications.**
- (4) The State claims that BMS "controlled" AWPs because there was a formulaic relationship between BMS's list prices and the AWPs that the Publications reported for its drugs. (Opp. at 8.) **This ignores the undisputed testimony that BMS did not control the Publications or how they calculated AWPs.**

We show below that the State cannot demonstrate that BMS made any misrepresentations -- it simply reported legitimate list prices to industry publications. We also show that there is no proof that BMS marketed the spread to anyone in Montana. Finally, we show that the State has failed to demonstrate causation.

Argument

I.

IT IS UNDISPUTED THAT BMS DID NOT MAKE ANY MISREPRESENTATIONS TO THE STATE.

A. BMS Did Not Report AWPs

The essence of the State's case is that the pharmaceutical manufacturers reported AWPs to the Publications, and the State then relied on those AWPs to establish reimbursement amounts for providers. It is undisputed, however, that BMS has never reported AWPs to the Publications. (Kaszuba Aff. ¶ 6; Kaszuba 11/13/06 Tr. 110, 113; DX 2595; DX 2650; Szabo Aff.

¶ 6; Rogers Aff. ¶ 2; Ihling Dep. Tr. 93; Declaration of Zoltan Szabo in Support of Defendant Bristol-Myers Squibb Company's Memorandum in Opposition to Plaintiffs' Motion for Class Certification ("Szabo Decl.") ¶ 6, annexed to Edwards Decl. as Ex. F.)¹ Rather, it has always reported its list prices. (Kaszuba Aff. ¶ 3; Kaszuba 11/13/06 Tr. 52, 58, 109; Rogers Aff. ¶¶ 1-2; Szabo Aff. ¶ 6; Ihling Dep. Tr. 89, 97; Szabo Decl. ¶ 5.)

The States' argument that BMS "owned" and "published" AWPs because it used them internally and "republished" them to doctors (Opp. at 5-6) is to no avail. The State does not claim that it relied on, or even saw, those AWPs. Nor does it claim that doctors reported them to the State.

Even if the Court were to assume that AWPs were deceptive, therefore, it is undisputed that BMS did not make any representations to the State about AWPs.

B. BMS's List prices Were Not Deceptive

BMS acknowledges that it reported list prices to the Publications. Those list prices, however, were the list prices that appeared on invoices to wholesalers. (Szabo Aff. ¶ 7; Rogers Aff. ¶ 4; Szabo Decl. ¶ 2.) Moreover, it is undisputed that BMS had substantial sales within 5% of those list prices. (See BMS Mem. at 5-6.)

¹ Class 2 and 3 trial testimony is cited by witness's last name, date and transcript page number (e.g., Smith xx/yy/zz Tr. 123). References herein to the witness's written direct testimony includes last name, the abbreviation "Aff." and a paragraph number, (e.g., Smith Aff. ¶ 1). Citations to deposition transcripts are in the same format as trial testimony, but include the abbreviation "Dep." after the witness's name instead of "Tr." References to "DX" or "PX" with a document number are references to trial exhibits in evidence. The declaration of Steven M. Edwards, dated February 8, 2007 ("Edwards Decl."), was proffered with BMS's moving papers for the limited purpose of placing certain additional record evidence before the Court. The merits report and declaration of Dr. Gregory K. Bell, Ph.D. on behalf of BMS, dated February 8, 2007 ("Bell BMS MT Decl."), was proffered with BMS's moving papers for the limited purpose of providing background information and presenting an analysis of the relationship of BMS transaction prices to list prices.

In contrast to the Class case, this case involves SADs sold to retail pharmacists who were reimbursed under Medicaid.² As to those drugs, BMS has demonstrated that it does not discount (or provide rebates) to retail pharmacies. (Bell BMS MT Decl. ¶¶ 9f-g, 18, 20, 21, 29-33, 37.) The State has not attempted to dispute that fact. (See Opp. at 16.)

With respect to the handful of physician-administered drugs at issue in this case, BMS has demonstrated that more than 86% of BMS's net revenues were achieved in transactions at prices that were within 5% of list price. (Bell BMS MT Decl. ¶ 13, Exh. F.) Even when those products lost their exclusivity and became subject to multi-source competition, BMS continued to achieve 27.4% of its net revenue from sales within 5% of list price. (Id. ¶ 15, Exh. F.)³ The State has not attempted to controvert these facts either.

The State contends that BMS should have adjusted its list prices to reflect these discounts. As we demonstrated in our opening memorandum, however, there is no such duty as a matter of law. (BMS Mem. at 10-11 & n.16.) The State fails to distinguish the cases cited by BMS.⁴

The State relies on Judge Stearns' opinion at the motion to dismiss stage in In re Lupron Marketing & Sales Practices Litig. to contend that BMS had a duty to disclose discounts. (Opp. at 12-13.) In Lupron, Judge Stearns assumed as true the allegations that the defendants

² The State's expert witness, Dr. Hartman, calculates no penalties for BMS physician administered drugs ("PADs"). (Hartman Montana Report, Table 5.) The overcharge damages he calculates for BMS's PADs total \$12,250. (Id., Table 1.) Dr. Hartman also calculates "J-code" overcharge damages for Taxol of \$50,850 (Id., Table 2), but he concedes: "This sum of overcharge damages is useful for illustration only, rather than as a basis for recovery for economic injury." (Id., ¶ 33(b).)

³ The State relies heavily on BMS's experience with respect to Taxol in 2002, which it describes as a "plenary example." (Opp. at 14.) Dr. Bell's testimony demonstrates that BMS's experience with respect to Taxol was unique because of a "timing problem" relating to chargebacks. (Bell 12/7/06 Tr. 42-43.) Moreover, even with the heavy discounts of Taxol in 2002, there were still significant sales -- in terms of dollar volume -- within 5% of list price. (Marre 11/14/06 Tr. 158-63; PX 207.)

⁴ For example, the State seeks to distinguish Langford v. Rite Aid of Ala., Inc., 231 F.3d 1308 (11th Cir. 2000) on the basis that "plaintiff consumers had no shopping choices." (Opp. at 13, n.15.) As the State admits, there are no consumer claims left in this action. Only claims by Montana Medicaid remain. (See Opp. at 2.) Montana Medicaid could have chosen numerous other reimbursement methods.

had engaged in affirmative misrepresentations because they reported AWPs. 295 F. Supp. 2d 148, 167-68 (D. Mass. 2003). Judge Stearns recognized that, in the absence of an affirmative misrepresentation, there is no duty to disclose discounts. Id. at 167.⁵

This Court recognized the same thing in Alves v. Harvard Pilgrim Health Care, Inc., 204 F. Supp. 2d 198, 212-14 (D. Mass. 2002), aff'd, 316 F.3d 290 (1st Cir. 2003), where the Court held that an ERISA plan, which gave its beneficiaries receipts that listed the "retail value" of prescription drugs, did not have to disclose that it had actually acquired the drugs at substantial discounts below retail value. The State attempts to distinguish Alves on the ground that the issue there was "whether a plan sponsor breached its fiduciary duty under ERISA" (Opp. at 13 n.17), but a fiduciary duty is generally deemed to enhance, not reduce, any duty to disclose. See, e.g., Chiarella v. United States, 445 U.S. 222, 235 (1980). The State's position that list prices must be adjusted to reflect discounts is wrong as a matter of law.

C. **BMS Could Not Ignore The Publications**

The State claims that "BMS was not required to volunteer its WLPs to pricing compendia." (Opp. at 9.) That assertion is simply wrong. A pharmaceutical manufacturer cannot market a drug unless it is listed in one or more industry compendia, such as Redbook, First DataBank and MediSpan. (Kaszuba Aff. ¶ 5; Kaszuba 11/13/06 Tr. 125-26; Ihling Dep. Tr. 124-25; Szabo Aff. ¶ 13; PX 188 at BM/AWP/00337640.) For this reason, since the early 1970s, BMS has reported prices and product descriptions to the Publications. (Rogers Aff. ¶¶ 1-2; Szabo Aff. ¶ 6; Ihling Dep. Tr. 89-97; see also Kaszuba Aff. ¶ 3; Kaszuba 11/13/06 Tr. 55, 109; Szabo Decl. ¶ 5.) If BMS had not sent WLPs to the Publications, providers could not have been reimbursed by Montana Medicaid for BMS drugs.

⁵ For this reason, the other cases relied upon by the State -- which involved half truths -- are not applicable here.

D. BMS Did Not Control the Publications

In support of its motion, BMS proffered significant evidence that it did not control how the Publications calculated AWPs. (Kaszuba 11/13/06 Tr. 110; DX 2545; DX 2587/PX 196 at BMS/AWP/00442095; DX 2588/PX 187 at BMS/AWP/01109782; DX 2589/PX 189 at BMS/AWP/01088211; DX 2595; DX 1137; Morgan Dep. Tr. 230.)⁶ BMS contended that, as a matter of law, it stands in the same position as a corporation that furnishes information to a securities analyst, which then alters that information and publishes it to the market. A corporation is not liable for the statements of an analyst that the corporation does not control. Eisenstadt v. Allen, No. 95-16255, 1997 WL 211313, at *15 (9th Cir. Apr. 28, 1997).

The State has not attempted to controvert BMS's position on either the facts or the law. Rather, it contends that BMS is liable for the Publications' actions because it is foreseeable that they will mark-up BMS's list prices by 20%-25% to calculate AWP. (Opp. at 3-4.) The MDL Court has already concluded in connection with the New York County cases that the Publications' 20%-25% mark-up does not violate the law. City of New York, et al. v. Abbott Laboratories, et al., Civ. Action No. 04-cv-06054, et al., April 2, 2007 Mem. & Order at 37 n.9 (Saris, J.) ("Only those drugs for which the plaintiffs have alleged a spread greater than the 20-25% mark up between WAC and AWP survive.").⁷

Furthermore, it is undisputed that the Publications (not BMS) decided what mark-up factor to apply to BMS's list prices to calculate the AWP.⁸ The Publications represented to

⁶ In addition, various BMS documents confirming that the publications control AWPs were received in evidence at the Class 2 and 3 Trial. (See DX 2545; DX 2554; DX 2585 at BMS/AWP/001510398; DX 2588/PX 187 at BMS/AWP/01109782; DX 2587/PX 196 at BMS/AWP/00442095; DX 2589/PX 189 at BMS/AWP/01088211; DX 2595 at BMS/AWP/00059757.)

⁷ The Court has observed on more than one occasion that "everyone knew about a 20 to 25 percent spread . . . Everyone knew, everyone." (4/11/07 Tr. at 22; see also 11/15/06 Tr. at 93.)

⁸ Indeed, plaintiff's counsel in the MDL Class 2/3 trial stipulated that BMS did not, prior to 1992, suggest to the Publications what mark-up factor should be used. (DX 2650.)

BMS that the mark-up factor they apply for BMS drugs was based on surveys they had made of drug wholesalers as to the list prices that wholesalers provide to their customers. (Kaszuba 11/13/06 Tr. 58-59, 114-16; see also Szabo Decl. ¶ 5.) BMS did not suggest the 20.5% to 25% mark-up factor that the Publications used. (Kaszuba 11/13/06 Tr. 58; DX 2650; Szabo Decl. ¶ 6; see also Szabo Aff. ¶ 6.)

The State asserts that BMS “did not leave the mark up to publisher discretion” (Opp. at 4), relying on the sole occasion in 1992 when BMS asked the Publications to change their mark-up factor on oncology products from 20.5% to 25%. Only Redbook acceded to that request; First DataBank and MediSpan refused – thus, further demonstrating that BMS did not control the Publications. (Kaszuba Aff. ¶ 13; Kaszuba 11/13/06 Tr. 60, 114; DX 2552; DX 2553; DX 2554; Szabo Aff. ¶ 6; Szabo Decl. ¶ 6.) Significantly, Montana uses First DataBank, not Redbook, as the source for its AWPs, so it could not have been deceived by the Redbook AWPs. The State points to no other evidence that BMS ever suggested a mark-up to the Publications.

The State also claims that, because BMS periodically reviewed the Publications’ AWPs for reasonableness, BMS controlled the AWPs. (Opp. at 3-4.) Denise Kaszuba of BMS testified, however, that she sporadically reviewed the AWPs for mathematical correctness, and to ensure that BMS’s list price was reported correctly. (Kaszuba 11/13/06 Tr. at 89-90, 120.) Checking the Publications’ AWPs to avoid mathematical errors and typos cannot, as a matter of law, be deemed to be “control”.

The State also criticizes BMS for allegedly failing to take action to publicize that the AWPs for its drugs did not include discounts. (Opp. at 7.) That assertion is simply untrue. Beginning in 1999, BMS included in its communications to the Publications a statement that its list prices did not include discounts. (Kaszuba Aff. ¶ 7; Kaszuba 11/13/06 Tr. 127-28; Szabo Aff.

¶ 6; DX 2627 at FDB-AWP-18630; Szabo Decl. ¶ 5.) An example shown to Kay Morgan of First Data Bank at her deposition states:

“Wholesale and Direct List Prices, including those for the products listed herein, may not reflect actual Bristol-Myers Squibb sale prices. Certain multisource products are always sold at lower special offer prices. All products may be subject to negotiated discounts, rebates and chargebacks.”

(Morgan Dep. Ex. 41, annexed to Edwards Decl. as Ex. G.) That disclosure had no impact on the way the Publications calculated AWPs. (Kaszuba Aff. ¶ 7; Kaszuba 11/13/06 Tr. 127-28; Szabo Aff. ¶ 6; Morgan Dep. Tr. 227.) This is further undisputed evidence that BMS did not control how the Publications calculated AWPs.⁹

It should be emphasized that this is not a case in which a party furnished misleading information to a third party who republished it. This is a situation in which a party furnished truthful information -- i.e. BMS’s list prices -- to a third party who adopted a mark-up of 20-25% and called it “AWP”.¹⁰ If there is liability under these circumstances, then any person who supplies a product or a service to another person could be liable for that other person’s acts. That is not the law.

II.

BMS DID NOT MARKET THE SPREAD

It is unclear what the State’s claim concerning marketing the spread adds to its case. If BMS is liable for making misrepresentations with respect to AWPs, marketing the

⁹ Similarly, in 2002, First DataBank unilaterally changed the mark-up factor on all drugs to 25% (Kaszuba Aff. ¶ 15) -- further demonstrating that BMS did not control AWPs.

¹⁰ The State relies on an Apothecon document to suggest that BMS raised its list price even though its average selling price did not change. (Opp. at 5.) As we have stated in the past, Apothecon was BMS’s generic subsidiary, and its business model was different from the business model pursued by BMS’s other groups. Montana seeks damages for only 2 claims relating to Apothecon drugs in this action. (Bell BMS MT Decl. ¶ 6.) Plaintiff also relies on a document relating to Etopophos to suggest that BMS manipulated the spread to influence provider decisions. (Opp. at 11-12.) The State’s own expert has admitted that the plan suggested in that document was never implemented. (Rosenthal Dep. Tr. 375-384) (relevant portion attached hereto as Exhibit A.)

spread does not add anything to the State's claim.¹¹ If BMS is not liable for making misrepresentations with respect to AWPs, it is difficult to see how it could become liable as a result of providing accurate information to providers about spreads.

In any event, there is no proof that BMS marketed the spread to any provider in Montana. The State's claim against BMS for SADs is limited to brand name drugs. Doctors, not pharmacists, decide whether a patient should receive a brand name drug. The State concedes that “[a]s to brand name drugs sold through pharmacies, physicians make clinical decisions to prescribe the drugs to their patients and have no economic interest in the transaction.” (See Pls' Response to BMS 56.1 Statement at ¶ 33; BMS 56.1 Statement at ¶ 33.)

With respect to PADs, BMS had a strict policy that spreads were to be discussed only in response to customer questions; sales representatives were not to initiate such discussions. (PX 223.) There is no proof that anyone violated this policy in Montana. The State's marketing the spread claim is without merit.

III.

THE STATE HAS NOT DEMONSTRATED CAUSATION

The State admits it must show that BMS's conduct caused it injury. (Opp. at 16.) While there are many reasons why the State cannot demonstrate causation, one reason stands out as dispositive: The State obviously knew “the truth” after it commenced this lawsuit but chose not to change its reimbursement formula. Under the circumstances, the State cannot prove that “but for” the alleged misrepresentations of BMS (which it has also failed to prove) it would have paid any less for drugs.

¹¹ The State essentially concedes this, noting that: “Even if the proof fails as to BMS's spread marketing as to self-administered drugs, the evidence is clear on BMS's submission of false AWPs for all categories of drugs.” (Opp. at 2.)

Conclusion

For the foregoing reasons, BMS's motion for summary judgment should be granted.

Dated: May 10, 2007

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Lyndon M. Tretter, certify that a true and correct copy of the Reply Memorandum of Law of Defendants Bristol-Myers Squibb Company, Oncology Therapeutics Network Corp. and Apothecon, Inc. In Support of Motion For Summary Judgment was served upon all counsel of record on May 10, 2007 by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending copies to Lexis-Nexis for posting and notification to all parties.

/s/ Lyndon M. Tretter
Lyndon M. Tretter